JUN 2 2 2001

Catheter Repair Kit with Replacement Connector

510(k) Summary of Safety and Effectiveness Information
21 CFR 807.92

1. Submitter Information:

Submitter Name:	Bard Access Systems, Inc. [Subsidiary of C. R. Bard, Inc.]
Address:	5425 W. Amelia Earhart Drive Salt Lake City, UT 84116
Telephone Number:	(801) 595-0700, Ext. 4903
Fax Number:	(801) 595 5425
Contact Person:	Peggy Keiffer
Date of Preparation:	April 3, 2001

2. Device Name:

Device Name:	Catheter Repair Kit with Replacement Connector
Trade Name:	Catheter Repair Kit
Common/Usual Name:	Catheter Repair Kit
Classification Name:	MSD Blood Access Device Accessory 21 CFR 876.5540 Class II
Classification Panel:	Gastroenterology and Renal

3. Predicate Device Name:

Device Name:	Modified Vas-Cath Catheter Repair Kit
Trade Name:	Vas-Cath Catheter Repair Kit
Common/Usual Name:	Catheter Repair Kit
Classification Name:	LFJ (MSD) Catheter, Subclavian (accessory) 21 CFR 876.5540, Class II
Classification Panel:	Gastroenterology and Renal

4. Device Description

The device description of the subject Catheter Repair Kit with Replacement Connector is as follows:

- The sterile Catheter Repair Kit consists of a white acetal replacement connector and replacement collar.
- The replacement connector has a luer connector on one end and an integrated tubing connector barb at the other.
- The replacement collar fits over the catheter extension tubing and is threaded over the connector barb onto the threaded portion of the luer connector, providing a compression fit of tubing and connector.
- Additional currently cleared kit accessories are included (red and blue clamps, drape, green temporary slide clamp, scissors, injection cap and a priming volume label).

The device is used by:

- Placing the internally threaded collar over the extension tubing
- Inserting the barbed portion of the replacement connector onto the extension tubing until the tubing is advanced over the barb of the connector
- Threading the collar onto the replacement connector, compressing the extension tubing on the barb.

5. Intended Use

To replace: Cracked or broken female luer lock connectors or repair damaged extension where there is a minimum of 4.5 cm of viable extension tubing on the following Vas-Cath catheters:

- Soft-Cell® Long-Term Dual Lumen Catheter
- Opti-Flow® Long-Term Dual Lumen Catheter
- Slim-Cath™ Temporary Dual Lumen Catheter
- Vaccess® Temporary Single Lumen Catheter
- Flexxicon® Temporary Dual Lumen Catheter
- Niagara™ Temporary Dual Lumen Catheter
- Flexxicon® II Temporary Dual Lumen Catheter

6. Technological Characteristics Summary:

6.1 Does the new device have the same indication statement?

The intended use is the same as the predicate Vas-Cath Catheter Repair Kit. However, the indication for use has been modified in that the use is more specifically described as limited to those damaged extensions where there is a minimum of 4.5 cm of viable extension tubing. The Vas-Cath hemodialysis catheters that can be repaired are all those that have the same size extension legs (13.5 French with 3mm inner diameter). This includes additional Vas-Cath hemodialysis catheters that have been cleared for

market since the 1989 predicate 510(k) and are specifically described in the indications for use.

6.2 Does the new device have the same technological characteristics, e.g. design, material, etc.?

Not in all respects. The principles of operation and basic design are the same. The titanium/polyester materials are replaced by acetal.

6.3 Could the new characteristics affect safety or effectiveness?

Yes. The integrity of the materials of the extension-connector interface could affect the safety or effectiveness of the device.

6.4 Do the new characteristics raise new types of safety and effectiveness questions?

No. There are no new issues of safety and effectiveness.

6.5 Do accepted scientific methods exist for assessing effects of the new characteristics?

Yes. The FDA's "Guidance on Premarket Notification [510(k)] Submission for Short-Term and Long-Term Intravascular Catheters", dated 3/16/95, and corresponding ISO Standards were used to evaluate the device's performance.

Biocompatibility meets the requirements of ISO-10993, " Biological Evaluation of Medical Devices Part-1: Evaluation and Testing: and the FDA Modified ISO 10993 Test Profile for externally communicating blood contacting long term devices.

6.6 Are performance data available to assess effects of new characteristics?

Yes. Bench testing was performed according to the above referenced guidance and standards. The results met the requirements of the appropriate ISO standards.

6.7 Do performance data demonstrate equivalence?

Yes. Performance data demonstrate that the Catheter Repair Kit with Replacement Connector is substantially equivalent to the predicate Vas-Cath Catheter Repair Kit, K890099.

6.8 Performance Data (if applicable).

The Catheter Repair Kit Replacement Connector tests were performed in accordance with the *Guidance on Premarket Notification [510(k)] Submission for Short-Term and Long-Term Intravascular Catheters*, dated 3/16/95. (Only those tests applicable to the luer connection were performed):

- Dimensions
- Tensile strength of catheter body to hub attachments (for this project, connector to extension leg attachment)
- Leakage at hub (connector – positive and negative pressure)
- Catheter burst pressure (positive internal pressure) (connector-extension leg interface)

Catheter guidance tests NOT required for this product change:

- Tensile strength of catheter body
- Catheter stiffness
- Catheter tip (distal) attachment strength
- Catheter elongation
- Catheter Collapse (negative internal pressure)
- Catheter flexural fatigue tolerance

The Catheter Repair Kit with Replacement Connector met all predetermined acceptance criteria of testing performed and, based on FDA's decision tree, are substantially equivalent to the predicate device, Vas-Cath Catheter Repair Kit, K890099, concurrence date April 11, 1989.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 2 2 2001

Mr. Glenn Norton
Sr. Regulatory Affair Specialist
Bard Access Systems, Inc.
5425 W. Amelia Earhart Drive
Salt Lake City, Utah 84116

Re: K011015
Catheter Repair Kit with Replacement Connector
Dated: April 3, 2001
Received: April 4, 2001
21 CFR §876.5540/Procode: 78 NFK

Dear Mr. Norton:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. However, you are responsible to determine that the medical devices you use as components in the kit have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were legally on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. *Please note:* If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval) it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action.

In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. *Please note:* this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal Laws or Regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market. If you desire specific advice for your device on the labeling regulation (21 CFR Part 801 and additionally §809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4616. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR §807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll free number (800) 638-2041 or (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for David G. Segerson

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K011015

Section I-D

Catheter Repair Kit with Replacement Connector

INDICATION(S) FOR USE STATEMENT*

I state in my capacity as Senior Regulatory Affairs Manager of Bard Access Systems, that this notification [510(k)] for the following devices, Catheter Repair Kits with Replacement Connectors, are indicated for the following:

To replace: Cracked or broken female luer lock connectors or repair damaged extension where there is a minimum of 4.5 cm of viable extension tubing on the following Vas-Cath catheters: Soft-Cell® Long-Term Dual Lumen Catheter, Opti-Flow® Long-Term Dual Lumen Catheter, Slim-Cath™ Temporary Dual Lumen Catheter, Vaccess® Temporary Single Lumen Catheter, Flexxicon® Temporary Dual Lumen Catheter, Niagara™ Temporary Dual Lumen Catheter, Flexxicon® II Temporary Dual Lumen Catheter.

Signature of 510(k) Submitter: Peggy Keiff

Printed Name of Submitter: Peggy Keiffer

Date: 4.3.01

*Suggested language and format to meet the requirements of sections 513(i) of the Federal Food, Drug, and Cosmetic Act, as amended, and sections 807.92(a)(5) and 801.4 of the Code of Federal Regulations, Title 21.

Concurrence of Office of Device Evaluation

510(k) Number _____

Division Sign-Off
Office of Device Evaluation

David A. Lyon
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K011015

Prescription Use ✓ OR Over-The-Counter Use _____